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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,506	06/13/2001	Donald K. Jones	CRD0935	5338

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EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 11/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,506	JONES ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14,16,17,20 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-14,16,17,20 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated October 7, 2003. Claims 1-4, 6-14, 16-17, 20 and 26 are pending.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 11, and 20 have been considered but are moot in view of the new ground(s) of rejection.

Applicant has amended claims 1 and 11 to include the limitation, "using an introducer that is coupled to the proximal portion." This limitation has not been previously presented and thus the basis for a new rejection.

Applicant has also amended the independent claims, 1, 11, and 20 to include the limitation, where the embolic coil includes "a proximal portion and a distal portion; said proximal portion being relatively smooth and said distal portion being relatively textured." This limitation, from dependent claims 5 and 15, was added to claims 1 and 11. However, this combination was not previously presented with respect to claim 20, thus the basis for a new rejection for claim 20.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the introducer that is coupled to the proximal portion must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4, 6-14, 16-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz et al. in US Patent No. 6,063,100 in view of Plowiecki in FR2696636 or Jacobsen et al. in US Patent No. 6,530,934.

Regarding claim 1, Diaz et al. disclose a method for occluding the vasculature of a patient, via providing a plurality of embolic coils having a proximal portion and a distal portion, the proximal portion being relatively smooth and the distal portion having a relatively textured surface and introducing said plurality of embolic coils into the patient's vasculature, as discussed throughout the specification and seen in figures 1-5. Further applicant's attention is drawn to pages 5 and 6 of the current application specification, which recites, "The roughness is uniform throughout the coil except if the coil is used with a detachment system as disclosed in Hieshima U.S. Patent No. 6,113,622 or Diaz et al. U.S. Patent No. 6,063,100, a proximal portion of the coil is not textured in order for it to have proper seal with a gripper so that is can [be] released easily."

However, Diaz et al. do not explicitly recite embolic coils that have a textured surface, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

On the other hand, Plowiecki teach a method for occluding the vasculature of a patient via providing a plurality of embolic coils having a textured surface; introducing the plurality of embolic coils into the patient's vasculature, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting, as stated in the abstract and seen in figure 1. Additionally, Jacobsen et al. teach a method for occluding the vasculature of a patient via providing a plurality of embolic coils having a textured surface; introducing the plurality of embolic coils into the patient's vasculature, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting, as recited in column 4, lines 48-65.

Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Diaz et al. to have a textured surface for the purpose of promoting clotting as taught by Plowiecki and Jacobsen et al. Furthermore, the end would necessarily remain smooth for proper deployment.

Regarding claims 2 and 12, Diaz et al. as modified by Plowiecki or Jacobsen et al. disclose the system as applied to claims 1 and 11. Further, although not explicitly recited, texturing the surface of an embolic coil by abrasion would be obvious to one with ordinary skill in the art. Texturing via methods such as

abrasion and sandblasting are well-known common methods and the current specification does not demonstrate the criticality of abrasion. Thus, when modifying the invention of Diaz et al. to include texturing for the purpose of promoting clotting, it would be obvious to use abrasion.

Regarding claims 3 and 13, Diaz et al. as modified by Plowiecki or Jacobsen et al. disclose the system as applied to claims 1 and 11. Further, although not explicitly recited, texturing the surface of an embolic coil by sandblasting would be obvious to one with ordinary skill in the art. Texturing via methods such as abrasion and sandblasting are well-known common methods and the current specification does not demonstrate the criticality of abrasion. Thus, when modifying the invention of Diaz et al. to include texturing for the purpose of promoting clotting, it would be obvious to use sandblasting.

Regarding claims 4 and 14, Diaz et al. as modified by Plowiecki or Jacobsen et al. disclose the system as applied to claims 1 and 11. Further, although not explicitly recited, an embolic coil that is a platinum-tungsten alloy wire would be obvious to one with ordinary skill in the art. Platinum-tungsten alloys are well known and used in the art. Further, the current specification does not demonstrate the criticality of platinum-tungsten. Thus, when modifying the invention of Diaz et al. to include texturing for the purpose of promoting clotting, it would be obvious to use a platinum-tungsten alloy for its superior properties for

use in the body. Moreover, Diaz et al. recite, "Embolic coils are generally formed of a radiopaque metallic materials, such as platinum, gold, tungsten or alloys of these metals. Often times several coils are placed at a given location in order to occlude the flow of blood through the vessel by promoting thrombus formation at the particular location." Thus, although a platinum-tungsten alloy is not explicitly recited, it is within the scope of the invention.

Regarding claims 6 and 16, Diaz et al. as modified by Plowiecki or Jacobsen et al. disclose the system as applied to claims 1 and 11. Further, although not explicitly recited, an embolic coil that has substantially uniform roughness with pockets having diameters between about 0.125 microns and about 50 microns would be obvious to one with ordinary skill in the art and within the scope of the invention. Further, the current specification does not demonstrate the criticality of an embolic coil that has substantially uniform roughness with pockets having diameters between about 0.125 microns and about 50 microns. In fact, page 5 of the specification recites, "***Although no limitation is intended***, as a specific example the texturization provides a uniform roughness comprising pockets having diameters between about 0.125 microns and about 50 microns and depths between about 0.25 microns and about 20 microns." Thus, when modifying the invention of Diaz et al. to include texturing for the purpose of promoting clotting, it would be obvious to assure that the embolic coil has substantially uniform roughness and has pockets having diameters between

about 0.125 microns and about 50 microns as within the scope of the invention although not explicitly recited.

Regarding claims 7 and 17, Diaz et al. as modified by Plowiecki or Jacobsen et al. disclose the system as applied to claims 6 and 11. Further, although not explicitly recited, an embolic coil that has pockets that have depths of between about 0.25 microns and about 20 microns would be obvious to one with ordinary skill in the art and within the scope of the invention. Further, the current specification does not demonstrate the criticality of an embolic coil that has pockets that have depths of between about 0.25 microns and about 20 microns. In fact, page 5 of the specification recites, "***Although no limitation is intended***, as a specific example the texturization provides a uniform roughness comprising pockets having diameters between about 0.125 microns and about 50 microns and depths between about 0.25 microns and about 20 microns." Thus, when modifying the invention of Diaz et al. to include texturing for the purpose of promoting clotting, it would be obvious to assure that the embolic coil that has pockets that have depths of between about 0.25 microns and about 20 microns as within the scope of the invention although not explicitly recited.

Regarding claims 8-10, Diaz et al. as modified by Plowiecki or Jacobsen et al. disclose the system as applied to claim 1 above. Claim 8 recites, "the embolic coils are used to embolize a vessel for vessel sacrifice." Claim 9 recites, "the

embolic coils are used to reduce or block blood flow to an arterial-venous malformation or to a fistula." Claim 10 recites, "the embolic coils are used to block blood flow to tumor." These claims are intended use and within the scope of the invention although not explicitly recited. Furthermore, the criticality for these intended use limitations have not been demonstrated in the specification of the current application. Furthermore, Plowiecki discloses that as applied to claim 9 and Jacobsen et al. discloses that as applied to claims 8 and 9.

Regarding claim 11, Diaz et al. disclose a method for treating an aneurysm of a patient, via providing a plurality of embolic coils having a proximal portion and a distal portion, the proximal portion being relatively smooth and the distal portion having a relatively textured surface and introducing said plurality of embolic coils into the patient's aneurysm, as discussed throughout the specification and seen in figures 1-5. Further applicant's attention is drawn to pages 5 and 6 of the current application specification, which recites, "The roughness is uniform throughout the coil except if the coil is used with a detachment system as disclosed in Hieshima U.S. Patent No. 6,113,622 or Diaz et al. U.S. Patent No. 6,063,100, a proximal portion of the coil is not textured in order for it to have proper seal with a gripper so that is can [be] released easily."

However, Diaz et al. do not explicitly recite embolic coils that have a textured surface, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

On the other hand, Plowiecki teach a method for occluding the aneurysm of a patient via providing a plurality of embolic coils having a textured surface; introducing the plurality of embolic coils into the patient's aneurysm, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting, as stated in the abstract and seen in figure 1. Additionally, Jacobsen et al. teach a method for occluding the aneurysm of a patient via providing a plurality of embolic coils having a textured surface; introducing the plurality of embolic coils into the patient's aneurysm, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting, as recited in column 4, lines 48-65.

Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Diaz et al. to have a textured surface for the purpose of promoting clotting as taught by Plowiecki and Jacobsen et al. Furthermore, the end would necessarily remain smooth for proper deployment.

Regarding claim 20, Diaz et al. disclose a embolic coil having a proximal portion and a distal portion, the proximal portion being relatively smooth and the distal portion, as discussed throughout the specification and seen in figures 1-5. Further applicant's attention is drawn to pages 5 and 6 of the current application specification, which recites, "The roughness is uniform throughout the coil except if the coil is used with a detachment system as disclosed in Hieshima U.S. Patent No. 6,113,622 or Diaz et al. U.S. Patent No. 6,063,100, a proximal portion of the

coil is not textured in order for it to have proper seal with a gripper so that is can [be] released easily." Moreover, Diaz et al. recite, "Embolic coils are generally formed of a radiopaque metallic materials, such as platinum, gold, tungsten or alloys of these metals. Often times several coils are placed at a given location in order to occlude the flow of blood through the vessel by promoting thrombus formation at the particular location." Thus an embolic coil formed of a platinum alloy wire is disclosed.

However, Diaz et al. do not explicitly recite an embolic coil having a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

On the other hand, Plowiecki teach a method for occluding the vasculature of a patient via providing a plurality of embolic coils having a textured surface; introducing the plurality of embolic coils into the patient's vasculature, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting, as stated in the abstract and seen in figure 1. Additionally, Jacobsen et al. teach a method for occluding the vasculature of a patient via providing a plurality of embolic coils having a textured surface; introducing the plurality of embolic coils into the patient's vasculature, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting, as recited in column 4, lines 48-65.

Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Diaz et al. to have a textured surface for the purpose of promoting clotting as taught by Plowiecki and Jacobsen et al. Furthermore, the end would necessarily remain smooth for proper deployment.

5. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Plowiecki in FR2696636.

Plowiecki discloses an embolic coil having a textured surface which when implanted in a patient's vasculature, provides improved platelet adhesion compared to a non-textured surface to promote clotting, the embolic coil including a proximal portion and a distal portion, as stated in the abstract and seen in figure 1.

However, Plowiecki does not explicitly recite a coil formed of a platinum alloy wire or a proximal portion that is relatively smooth and the textured surface being on the distal portion where the textured portion has a substantially uniform roughness having pockets with diameters between about 0.125 microns and about fifty microns and depths between about 0.25 microns and twenty microns.

On the other hand, it would have been obvious to one with ordinary skill in the art to modify the invention of Plowiecki to have the coil that made of platinum alloy wire. The specification of the current application does not demonstrate the criticality for a platinum-tungsten alloy wire. Therefore, the wire of Plowiecki can be considered an equivalent since the function of promoting rapid clotting is achieved. Moreover, an embolic coil that includes a proximal portion and a distal portion where the proximal portion is relatively smooth and the distal portion that is relatively textured; an embolic

coil that has substantially uniform roughness pockets having diameters between about 0.125 microns and about 50 microns; pockets that have depths of between about 0.25 microns and about 20 microns; embolic coils are that are used to embolize a vessel for vessel sacrifice; and embolic coils that are used to block blood flow to tumor are within the scope of the invention and the roughened surface would fall in the range claimed. [There are numerous coils that show smooth tips – for example those with plugs, etc. See additional cited references. Therefore, it would be obvious to modify the invention of Plowiecki to have a proximal portion that is smooth for ease of insertion.]

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. in US Patent No. 6,530,934.

Jacobsen et al. disclose an embolic coil having a textured surface which when implanted in a patient's vasculature, provides improved platelet adhesion compared to a non-textured surface to promote clotting, the embolic coil including a proximal portion and a distal portion, as recited in column 4, lines 48-65.

However, Jacobsen et al. do not explicitly recite a coil formed of a platinum alloy wire or a proximal portion that is relatively smooth and the textured surface being on the distal portion where the textured portion has a substantially uniform roughness having pockets with diameters between about 0.125 microns and about fifty microns and depths between about 0.25 microns and twenty microns.

On the other hand, it would have been obvious to one with ordinary skill in the art to modify the invention of Jacobsen et al. to have the coil that made of platinum alloy wire. The specification of the current application does not demonstrate the

criticality for a platinum-tungsten alloy wire. Therefore, the wire of Jacobsen et al. can be considered an equivalent since the function of promoting rapid clotting is achieved. Moreover, an embolic coil that includes a proximal portion and a distal portion where the proximal portion is relatively smooth and the distal portion that is relatively textured; an embolic coil that has substantially uniform roughness pockets having diameters between about 0.125 microns and about 50 microns; pockets that have depths of between about 0.25 microns and about 20 microns; embolic coils are that are used to embolize a vessel for vessel sacrifice; and embolic coils that are used to block blood flow to tumor are within the scope of the invention and the roughened surface would fall in the range claimed.

[There are numerous coils that show smooth tips – for example those with plugs, etc. See additional cited references. Therefore, it would be obvious to modify the invention of Jacobsen et al. to have a proximal portion that is smooth for ease of insertion.]

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,231,590 and US Patent No. 6,299,627.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700